

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: GLUCAGON-LIKE	:	CIVIL ACTION
PEPTIDE-1 RECEPTOR AGONISTS	:	
(GLP-1 RAS) PRODUCTS	:	
LIABILITY LITIGATION	:	
	:	
	:	
THIS DOCUMENT RELATES TO:	:	MDL No. 3094
	:	2:24-md-3094-KSM
<i>ALL ACTIONS/ALL CASES</i>	:	
	:	

**PLAINTIFFS' REPLY BRIEF IN FURTHER SUPPORT OF
THEIR MOTION TO PERMIT MARKETING DISCOVERY OR TO
RECONSIDER ORDER PRECLUDING MARKETING DISCOVERY**

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On September 6, 2024, Plaintiffs filed their Motion to Permit Marketing Discovery or to Reconsider Order Precluding Marketing Discovery (Doc. No. 245) (the “Motion”);¹ and Defendants filed their Joint Opposition thereto on September 20, 2024 (Doc. No. 254) (the “Opposition”). To be clear, contrary to the position taken by Defendants in the Opposition, Plaintiffs are not asking the Court to revisit the decision to bifurcate nor are they asking the Court to “front-load ‘marketing’ discovery” or permit individual, case-specific marketing discovery. *E.g.*, Opp. at 1. Having read the Opposition, there is one area upon which the Parties agree—the purpose of the Court’s decision regarding bifurcation is to enable it to efficiently decide certain issues that apply across cases in this MDL. *See* Case Management Order No. 18 (Doc. No. 235) (“CMO 18”), ¶ 14. Defendants’ insistence that CMO 18 contains a blanket prohibition on “marketing discovery” does the opposite and ensures that the Court will be unable to eliminate any cases from the MDL based on preemption and or the adequacy of the Defendants’ warnings.

Notably, to date, Defendants have ***not cited a single case*** where the issue of the adequacy of defendant’s warnings and preemption were decided at summary judgement without the availability of “marketing” discovery. The Parties initial briefing on this issue focused on bifurcation with little discussion of discovery, much less marketing discovery. *See* Doc. 175 at 12; Doc. 174 at 6. Defendants cited 2 cases for the proposition that the adequacy of the warnings and preemption were appropriate for a summary judgment disposition (Doc. 175 at 7)—*Taxotere* and *Meridia*—but in ***neither*** of those cases did the issues get decided ***without the benefit of discovery, including marketing discovery.***² Defendants’ inability to cite a case where this novel approach of

¹ Plaintiffs’ Memorandum of Law in Support of the Motion (Doc. No. 245-1) is referenced herein as “Opening Brief,” “Brief,” or “Br.”

² *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 462 F. Supp. 3d 650, 652-53 (E.D. La. 2020) (summary judgment after case-specific discovery and during a bellwether process); *see also In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 821-23 (N.D. Ohio 2004) (discussing marketing

prohibiting “marketing discovery” has been ordered by a court makes sense because it is well understood that the issues in Issue 2 ought not be decided without such discovery.

Instead, Defendants want this Court to believe that all that is required to make its determinations as to Issue 2 is to look at the printed label affixed to the bottle and some FDA correspondence. *E.g.*, Opp. at 1, 6. This is contrary to well-settled law, including a new Third Circuit decision, which emphatically reaffirmed that:

Although we commonly understand a drug’s ‘label’ to refer to the sticker affixed to a prescription bottle, ***in this context the term refers more broadly to the written material that is sent to the physician who prescribes the drug and the written material*** that comes with the prescription bottle when the drug is handed to the patient at the pharmacy. These (often lengthy) package inserts contain detailed information about the drug’s medical uses and health risks.

In re: Fosamax (Alendronate Sodium) Prod. Liab. Litig., 2024 WL 4247311, at *1 n.2 (3d Cir. Sept. 20, 2024) (quoting *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 303-04 (2019)) (emphasis added). As the Third Circuit’s decision in *Fosamax*, governing regulations, and relevant case law illustrate, the content of the label and determination of the adequacy of the warnings (and preemption) are based on much more than “the sticker affixed to the prescription bottle” and extend to the whole of the materials disseminated by the Defendants (including marketing materials).³

Plaintiffs file this Reply Brief to clarify the following three narrow points in advance of the Parties’ upcoming oral presentation:

evidence adduced during discovery), *aff’d sub nom. Meridia Prod. Liab. Litig. v. Abbott Lab’ys*, 447 F.3d 861 (6th Cir. 2006). The other cases cited by Defendants dealt with general causation. Doc. 174 at 6.

³ Defendants’ Opposition focuses heavily on the standard for reconsideration. Opp. at 1-4. The Parties disagree as to the extent that “marketing discovery” was previously briefed and argued but regardless of how the Motion is styled, the key issue is permitted CMO 18 to achieve its intended efficiencies. Plaintiffs discuss the relevant standard in Section 3, *infra*.

- (1) the Court cannot make any meaningful rulings regarding the adequacy of Defendants' warnings or preemption without "marketing discovery";
- (2) Plaintiffs only seek to clarify that the Court did not intend a blanket prohibition on "marketing discovery" in CMO 18 and that any requested "marketing discovery" can reasonably be managed through the normal discovery process; and
- (3) If CMO 18 does contain a blanket prohibition on "marketing discovery," lifting such a prohibition is required to prevent manifest injustice.

1. The Court cannot make any meaningful rulings regarding the adequacy of Defendants' warnings or preemption without "marketing discovery"

Defendants would like the Court to believe that a review of the companies' regulatory, medical, and scientific files are all that is required to make these cross-cutting determinations. *E.g.*, Opp. at 2, 5. That position is wrong. In the first instance, the Court will determine the contents of the "label" so that it can assess the full scope of the warnings provided. The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, identifies promotional labeling as another type of labeling for drugs. *See* 21 U.S.C § 321(m). Promotional labeling is generally, any labeling, other than FDA-required labeling that is devised for the promotion of a prescription drug. Examples of promotional labeling for prescription drugs are described in 21 CFR 202.1(1)(2) (emphasis added):

Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, . . . of the drug and which are disseminated by or on behalf of its manufacturer . . . are hereby determined to be labeling as defined in section 201(m) of the act.

See also Fosamax, 2024 WL 4247311, at *1 n.2 (quoting *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 303-04 (2019) to note that the label exceeds the materials "affixed to a prescription bottle[.]"). Strictly within the governing statutes and regulations, the Court cannot assess the label

without seeing the full panoply of these materials which Defendants would characterize as “marketing.”

Beyond that initial inquiry, the totality of information provided to a physician is relevant to assessing the “label” and the adequacy of the warning. According to the FDA, spending by pharmaceutical companies to market prescription drugs directly to healthcare professionals actually outpaces spending on direct-to-consumer promotion by more than 3-to-1.⁴ Under the FDCA and FDA regulations, promotional labeling for drugs that omits information about the risks is deemed to mislead as to the risks of a drug. *See, e.g.*, 21 U.S.C. §§ 352(a), (c); 21 U.S.C. § 321(n). And with good reason, appropriate risk disclosures help healthcare professionals have information that they need to safely prescribe drugs. Despite the importance of this information, “omission or minimization of risk information is the most frequent violation of the regulations cited in advertising or promotion [FDA] enforcement letters sent to [pharmaceutical drug companies].”⁵ As FDA has noted, the failure to adequately communicate important warnings in marketing is “concerning from a public health perspective because it creates a misleading impression regarding the overall safety of [drugs.]”⁶ Such concerns were evident in the context of similarly extensive marketing by manufacturers of opioids, where elevated rates of mortality were documented in counties subject to extensive marketing to prescribers.⁷

⁴ *See* The FDA Bad Ad Program and Prescription Drug Promotion, available at: https://www.accessdata.fda.gov/cder/ba/landingPage/CDER_BadAd_Course_Transcript.pdf (last accessed Sept. 22, 2024).

⁵ FDA Guidance for Industry, *Presenting Risk Information in Prescription Drug and Medical Device Promotion* (2009).

⁶ *E.g.*, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/alkermes-inc-597260-12022019>

⁷ Hadland, *et al.*, *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related Overdoses* (JAMA) 2019.

Dating as far back as 1982, the FDA has treated promotional labeling from advertisements as capable of influencing health care providers' understanding of the risks of a drug.⁸ *See also* U.S. Dept. of Health & Human Services, FDA, *Draft Guidance For Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion*, 4 (2009) (available at <https://www.fda.gov/media/76269/download>) (“It is important to emphasize that when FDA evaluates the risk communication in a promotional piece, FDA looks not just at specific risk-related statements, but at the net impression – *i.e.*, the message communicated by all elements of the piece as a whole.”). This understanding aligns with the relevant case law. For example, under Pennsylvania law, warnings accompanying a drug “are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, ***taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him,***” to decide “whether to prescribe a given drug.” *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 924 (Pa. Super. 2011) (emphasis added); *see also Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984); *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971). The impact of this advertising is distinct from Defendants repeated references to the impact of direct-to-consumer marketing on *Plaintiffs*. *E.g.*, Opp. at 5-7; *see, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prod. Liab. Litig.*, 181 F. Supp. 3d 278, 308–10 (E.D. Pa. 2016) (“marketing and advertising may be relevant to the plaintiff’s theory that the defendants’ branding of Extra Strength Tylenol ‘blunted’ the warnings provided”).

⁸ *See, e.g., Avorn, et al., Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, Am. J. Med. (July 1982); *Price, et al., What Influences Healthcare Providers’ Prescribing Decisions? Results from a National Survey*, J. Social Admin. Pharm. (Jan. 2021) (“[s]tudies show that industry marketing of prescription drugs results in less evidence-based prescribing and a greater likelihood of prescribing industry-promoted products even when other drugs are available that are equally as effective and have more established safety records.”).

The concerns that inform the FDA’s position are clearly present in this case and with these Defendants. Defendants’ marketing programs have sought to downplay the true nature of the risks of their GLP1 drugs and to promote the drugs for unapproved uses. *See* Ex. “A” (In response to Lilly proposed marketing to prescribers, FDA stated “[t]hese claims . . . are misleading because they omit important material information regarding gastrointestinal events associated with Trulicity.”); Ex. “B” (Novo proposed marketing to doctors “may create the misleading impression that Ozempic is indicated for weight loss, when this is not the case”). Plaintiffs also know that Novo’s paid speakers have echoed this effort to downplay the risks of Defendants’ GLP1 drugs in promotional advertising of the drugs,⁹ and that prescribers are receiving information directly from Defendants in numerous and expansive ways.¹⁰

The discovery of these direct communications go to the core issues of not only the label, as discussed above, but also of the extent to which Defendants downplayed certain risks (*e.g.*, gastroparesis) or the severity of certain risks, rendering the warnings inadequate.¹¹ *See, e.g., In re Bard IVC Filters Prod. Liab. Litig.*, 969 F.3d 1067, 1072 (9th Cir. 2020) (affirming jury verdict, applying Georgia law on failure to warn where district found that evidence supported a finding that “Bard chose not to warn physicians and instead downplayed the risk”). This is especially vital here where the Defendants’ drugs are among the most heavily marketed drugs and are part of a

⁹ *E.g.*, <https://www.cbsnews.com/news/wegozy-ozempic-explainer-60-minutes-2023-01-01/> (downplaying risk of nausea and vomiting with Wegovy)

¹⁰ *E.g.*, <https://www.youtube.com/watch?v=nCZR6wK7MIU>, Utilizing Advanced Marketing Analytics for Sales Optimization, Peter Vester, Novo Nordisk.

¹¹ Defendants have a history of downplaying risks. *See, e.g.*, U.S. Dept. of Justice, *Novo Nordisk Agrees to Pay \$58 Million for Failure to Comply with FDA-Mandated Risk Program* (Sept. 5, 2017), *available at*: <https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program>; U.S. Dept. of Justice, *Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa* (Jan. 15, 2009), *available at*: <https://www.justice.gov/archive/opa/pr/2009/January/09-civ-038.html>.

marketing program that seeks to optimize promotion to doctors through sophisticated marketing tactics, marketing analytics and data science.

Defendants’ attempt to minimize “marketing” evidence by claiming there are merely “potential ways in which [it] might theoretically apply in some unspecified case” misses the mark. To illustrate, CMO 18 uses as an example that if “a given label, as a matter of law, adequately warned for gastroparesis or that federal law preempts state law claims to the extent state law would have required the addition of a gastroparesis warning, [it] could limit many of the claims in this MDL or at minimum, hone the parties’ arguments as they relate to Defendants’ alleged failure to warn.” CMO 18 ¶ 12. But, to reach such a conclusion as to whether the label “adequately warned for gastroparesis,” the Court would need to consider the aforementioned ways in which Defendants marketed and promoted to prescribers. To use the example from CMO 18, if Defendants explicitly warned for gastroparesis (which they do not) but then sent promotional materials to doctors downplaying the risk, paid key opinion leaders to downplay the risk of gastroparesis, or published papers calling into question the real risk of gastroparesis, the gastroparesis “warning” would be inadequate.

Finally, the relevance and necessity of this “marketing” information to the determination of the adequacy of the Defendants’ warnings and whether any claims are preempted is not undermined by the learned intermediary doctrine, in fact, it is the opposite.¹² *See* Opp. at 2, 5, 7. The entire premise of the learned intermediary doctrine is that the physician has become educated as to the effects of a drug and can make reasonable recommendations on that basis. *See, e.g., McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006) (“The doctrine of the ‘learned intermediary’

¹² CMO 18 references the learned intermediary doctrine but again does in relation to “the legal effect, if any, of Defendants’ unique and substantial campaign to market the GLP-1 Ras directly to consumers.” ¶ 13.

presupposes that the physician will act as an intermediary. . . . inadequate labeling could be a ‘producing’ cause of the injury, because it effectively sabotages the function of the intermediary.”).

The *totality* of information provided to the physician or prescriber impacts directly on that issue.

2. *Plaintiffs only seek to clarify that the Court did not intend a blanket prohibition on “marketing discovery” in CMO 18 and that any requested “marketing discovery” can reasonably be managed through the normal discovery process*

As noted above, Plaintiffs are *not* seeking a license to conduct wide-ranging discovery that renders the Court’s bifurcation order meaningless as Defendants suggest. *E.g.*, Opp. at 1. Instead, Plaintiffs are asking the Court to clarify that it did not intend to issue a blanket prohibition against “marketing discovery” in CMO 18, or to the extent that it did, to lift such a prohibition. *E.g.*, CMO 18 ¶ 12 (no “need to know the specific ‘injuries claimed by [any individual] Plaintiff’”), ¶ 12 n.6 (discussing case-specific discovery), ¶ 13 (referring to marketing “directly to consumers”), ¶ 13 n.8 (discussing “marketing to a specific Plaintiffs” before referring to “pursuing discovery into Defendants’ marketing campaigns”). In the absence of such a blanket prohibition, Plaintiffs can conduct discovery consistent with normal practice which includes conducting meet and confers with Defendants in good faith regarding requests for “marketing discovery” that are relevant and proportional to the needs of determining Issue 2 in this case, and to the extent the Parties cannot agree, the Parties have the able assistance of Judge Stengel to move the process along efficiently.

3. *If CMO 18 does contain a blanket prohibition on “marketing discovery,” lifting such a prohibition is required to prevent manifest injustice*

Contrary to Defendants argument, the Motion is not an attempt to get the Court to “rethink” its decision on bifurcation or render such ruling meaningless. Opp. at 1-4. There is no doubt that the briefs on cross-cutting issues were focused on bifurcation with little mention of discovery, much less “marketing” discovery. *See* Doc. 174 at 5-7; Doc. 175 at 10-13. While it was raised at several conferences, it was in the context of case-specific discovery. *See, e.g.*, Tr. of 7/10/24 Status

Conference, at 74:21-25 (“Neither the preemption warning issue or the general causation issue requires state case-specific discovery to resolve the issue.”); Tr. of 8/2/24 Status Conference, at 7:2-7 (“And Plaintiffs made some statements about obligations running directly to patients.”). As noted above and in Plaintiffs Brief, Plaintiffs believe that CMO 18 reflects this distinction and that the availability of “marketing discovery” was not fully briefed and argued previously.

Nonetheless, if CMO 18 does contain a blanket prohibition on “marketing discovery,” lifting such a prohibition is required to prevent manifest injustice. *See, e.g., LM Gen. Ins. Co. v. LeBrun*, 2020 WL 7640927, at *4 (E.D. Pa. Dec. 23, 2020) (Marston, J.) (noting dearth of Third Circuit caselaw on what constitutes “manifest injustice”). As discussed above, the relevant regulations and governing law require that all communications from Defendants, including “marketing,” be considered when evaluating the adequacy of the warnings and preemption.

* * *

For the foregoing reasons and those set forth in Plaintiffs’ Opening Brief, the Motion should be granted and any blanket prohibition on “marketing discovery” should be lifted with any disputes over the scope and substance of that discovery dealt with through the normal discovery process.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2024, I filed the foregoing motion with the Clerk of the Court using the CM/ECF system. I also certify that the foregoing document is being served concurrently on all counsel of record via the Court's CM/ECF filing system.

/s/ Paul Pennock
Paul Pennock